

owner; lay user lessee, hospital, nursing home, outpatient diagnostic facility, outpatient treatment facility, ambulatory surgical facility);

(ii) Distributor report number;

(iii) Name, address, and telephone number of the reporting distributor and the source that reported the event to the distributor; and

(iv) Name of the manufacturer of the device.

(2) Date information.

(i) The date of the occurrence of the event;

(ii) The date the source that reported the event to the distributor became aware of the event;

(iii) The date the event was reported to the manufacturer and/or FDA; and

(iv) The date of this report.

(3) The type of MDR reportable event, e.g., death, serious illness, serious injury, or malfunction, and whether an imminent hazard was involved;

(4) Patient information including age, sex, diagnosis, and medical status immediately prior to the event and after the event;

(5) Device information including brand and labeled name, generic name, model number or catalog number or other identifying numbers, serial number or lot number, purchase date, expected shelf life/expiration date (if applicable), whether the device was labeled for single use, and date of implant (if applicable);

(6) Maintenance/service information data including the last date of service performed on the device, where service was performed, whether service documentation is available, and whether service was in accordance with the service schedule;

(7) Whether the device is available for evaluation and, if not, the disposition of the device;

(8) Description of the event.

(i) Who was operating or using the device when the event occurred;

(ii) Whether the device was being used as labeled or as otherwise intended;

(iii) The location of the event;

(iv) Whether there was multi-patient involvement, and if so, how many patients were involved;

(v) A list of any other devices whose performance may have contributed to

the event and their manufacturers, and the results of any analysis or evaluation with respect to such device (or a statement of why no analysis or evaluation was performed); and

(vi) A complete description of the event including, but not limited to, what happened, how the device was involved, the nature of the problem, patient followup/treatment required, and any environmental conditions that may have influenced the event.

(9) The results of any analysis of the device and the event, including:

(i) The method of evaluation or an explanation of why no evaluation was necessary or possible;

(ii) The results and conclusions of the evaluation;

(iii) The corrective actions taken; and

(iv) The degree of certainty concerning whether the device caused or contributed to the reported event;

(10) The name, title, address, telephone number, and signature of the person who prepared the report.

#### **§ 804.30 Annual certification.**

(a) All distributors required to report under this section shall submit an annual certification report to FDA, on FDA Form 3381, or electronic equivalent as approved under § 803.14 of this chapter. The date for submission of certification coincides with the date for the firm's annual registration, as designated in § 807.21 of this chapter. The certification period will be the 12-month period ending 1 month before the certification date, except that the first certification period shall cover at least a 6-month period from the effective date of this section, ending 1 month before the certification date.

(b) The distributor shall designate, as the certifying official, an individual with oversight responsibilities for, and knowledge of, the firm's MDR reporting system. A distributor may determine, based upon its organizational structure, that one individual cannot oversee or have complete knowledge of the operation of the reporting system at all organizational components or distribution sites owned by the firm. In this circumstance, the firm may designate more than one certifying official (one for each component or site),

each of whom will sign a certification statement pertaining to their respective identified organizational component(s) or site(s), provided that all organizational components and sites are covered under a certification statement.

(c) The report shall contain the following information:

(1) Name, address, and FDA registration number or FDA assigned identification number of the firm;

(2) Name, title, address, telephone number, signature, and date of signature of the person making the certification;

(3) Name, address, and FDA registration number or FDA assigned identification number for the distributor covered by the certification, and the number of reports submitted for devices distributed by the distributor;

(4) A statement certifying that:

(i) The individual certifying for the firm has read the MDR requirements under part 804;

(ii) The firm has established a system to implement MDR reporting;

(iii) Following the procedures of its MDR reporting system, the firm submitted the specified number of reports, or no reports, during the certification period; and

(iv) The certification is made to the best of the certifying official's knowledge and belief.

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**§ 804.31 Additional requirements.**

Requests for additional information. If FDA determines that the protection of the public health requires information in addition to that included in the medical device reports submitted to FDA under this part, the distributor shall, upon FDA's request, submit such additional information. Any request by FDA under this section shall state the reason or purpose for which the information is being requested, and specify a due date for the submission of such information.

**§ 804.32 Supplemental information.**

(a) Only one MDR is required under this part if the distributor becomes aware, from more than one source, of information concerning the same patient and the same event.

(b) An MDR that would otherwise be required under this section is not required by the distributor if:

(1) The distributor determines that the information received is erroneous in that a death, serious injury, serious illness, or the malfunction did not occur; or

(2) The distributor determines that the information received is erroneous in that the device that is the subject of the information was distributed by another distributor. A distributor shall forward to FDA any report that is erroneously sent to the distributor, with a cover letter explaining that the product in question is not distributed by that firm.

(c) A report or information submitted by a distributor under this part (and any release by FDA of that report or information) does not necessarily reflect a conclusion by the party submitting the report or by FDA that the report or information constitutes an admission that the device, the establishment submitting the report, or employees thereof, caused or contributed to a death, serious injury, serious illness, or malfunction. A distributor need not admit, and may deny, that the report or information submitted under this part constitutes an admission that the device, the party submitting the report, or employees thereof, caused or contributed to a death or serious injury, serious illness, or malfunction.

**§ 804.33 Alternative reporting requirements.**

(a) Distributors may request exemptions from any or all of the reporting requirements in this part. These requests are required to be in writing and to include both the information necessary to identify the firm and device and an explanation why the request is justified.

(b) FDA may grant a distributor, in writing, an exemption from any or all of the reporting requirements in this part and may change the frequency of reporting to quarterly, semiannually, annually, or other appropriate time periods. In granting such exemptions, FDA may impose other reporting requirements to ensure the protection of public health and safety. FDA may also